

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NEW YORK

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FARM SANCTUARY, <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 6:19-cv-6910-EAW-MWP
	)	
U.S. DEPARTMENT OF	)	
AGRICULTURE, <i>et al.</i> ,	)	
	)	
Defendants.	)	
_____	)	

DEFENDANTS' MEMORANDUM IN SUPPORT OF CROSS-MOTION FOR  
SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR  
SUMMARY JUDGMENT

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## INTRODUCTION

In 2019, following more than a decade of pilot testing, the Department of Agriculture (USDA) published a Final Rule that gives swine slaughter establishments the option to operate under a New Swine Slaughter Inspection System (NSIS). *See* USDA, *Modernization of Swine Slaughter Inspection*, 84 Fed. Reg. 52300 (Oct. 1, 2019) (codified at 9 C.F.R. pts. 301, 309 & 310) (Final Rule). Under that new system, which is implemented by USDA’s Food Safety and Inspection Service (FSIS), FSIS inspectors conduct an ante-mortem examination of every market hog presented for slaughter by a participating establishment, just as they have long been required to do by the Federal Meat Inspection Act of 1906 (FMIA). *See* 21 U.S.C. § 603. Before those inspections occur, establishment personnel sort the hogs, separating those they deem fit for slaughter from those suspected of having certain condemnable conditions or diseases. This aspect of the Final Rule—pre-inspection sorting of market hogs by establishment employees—is mandatory for establishments that opt to participate in NSIS, whereas under the traditional inspection system such pre-inspection sorting is voluntary. Regardless, under NSIS, any animal that the establishment intends to slaughter for human consumption requires inspection by a qualified FSIS inspector.

Plaintiffs, a collection of animal welfare groups, sued USDA to challenge these ante-mortem inspection provisions of the Final Rule under the Administrative Procedure Act (APA). Plaintiffs’ lawsuit and Motion for Summary Judgment, however, betray a fundamental misunderstanding of how ante-mortem inspection operates under NSIS. *See* Pls.’ Mot. for Summ. J., ECF No. 86 (Pls.’ Mot.). Plaintiffs believe that establishment personnel have *replaced* qualified federal inspectors, and that USDA has therefore outsourced its inspection obligations under the FMIA to the regulated industry. Nothing could be further from the truth. USDA was clear in the Final Rule that “FSIS inspectors still conduct 100 percent ante-mortem inspection” and that “FSIS inspectors inspect every market hog offered for slaughter.” 84 Fed. Reg. at 52312.<sup>1</sup> When measured against an accurate understanding of

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<sup>1</sup> Throughout this memorandum, when citing to a notice of proposed rulemaking or final rule, USDA provides the Federal Register citations, although those materials are also included in the Administrative Record (AR), ECF Nos. 58-60, 65. The Proposed Rule and Final Rule at issue in this case, for example, are in the record at AR100207-50 (Proposed Rule) and AR100251-300 (Final Rule).

how ante-mortem inspection operates under NSIS, Plaintiffs' arguments that USDA has abandoned its inspection obligations, violated the governing statutes, and delegated its authority to untrained slaughterhouse employees are meritless.

Plaintiffs also misread the record when they contend that USDA's issuance of the Final Rule was arbitrary and capricious. Contrary to Plaintiffs' claims, USDA considered the humane handling impacts of adopting NSIS, and determined that doing so would not adversely affect animal welfare under the Humane Methods of Slaughter Act (HMSA) relative to the status quo. *See* 7 U.S.C. § 1902. Likewise, USDA duly considered whether mandatory training for establishment employees was necessary for their pre-inspection sorting duties under NSIS. The fact that USDA did not adopt Plaintiffs' preferred policy on employee training does not render the Final Rule invalid. Also contrary to Plaintiffs' assertions, USDA considered the impacts of the Final Rule on agency staffing, concluding that staffing reductions would not negatively affect food safety or animal welfare. Finally, the ante-mortem inspection aspects of NSIS are not a reversal of a longstanding agency policy as Plaintiffs contend, and similar pre-inspection sorting processes have for years been employed by most establishments operating under the traditional inspection system. There was accordingly no heightened requirement for USDA to explain its reasons for adopting a purported change. In any event, USDA readily acknowledged that NSIS was a change from the traditional system, and more than adequately explained the reasons that it was adopting this new approach. The ante-mortem inspection provisions of the Final Rule are not arbitrary and capricious.

For all of the reasons that follow, Plaintiffs' Motion for Summary Judgment should be denied, and summary judgment should be entered in Defendants' favor.

### **BACKGROUND**

The 2019 Final Rule Plaintiffs challenge in this case allows qualifying market hog slaughter establishments, at their option, to adopt a new inspection system, dubbed the New Swine Slaughter Inspection System or NSIS. This voluntary system, as set forth in the Final Rule, contains three key elements: (1) it requires establishment employees to perform ante- and post-mortem sorting activities before federal inspection; (2) it requires establishment employees to trim and identify defects on

animal carcasses and parts before post-mortem inspection by FSIS inspectors, reducing the number of online FSIS inspectors to a maximum of three per line and enabling USDA to shift some resources from online inspection to offline inspection activities; and (3) it revokes maximum line speeds and allows establishments to set their own speeds based on their ability to maintain process control.<sup>2</sup> 84 Fed. Reg. 52300.

This third element—the revocation of maximum line speeds for evisceration lines—was enjoined by a Minnesota district court in 2021, and USDA did not appeal the decision. *See United Food & Commercial Workers Union, Local No. 663 v. USDA*, 532 F. Supp. 3d 741 (D. Minn. 2021) (*UFCW*). As a result of the injunction in *UFCW*, the line-speed aspect of the Final Rule is no longer in effect, and Plaintiffs chose to dismiss their erstwhile challenges to it under the APA and the NEPA—which they had pled in this case as their second and third causes of action. *See* First Am. Compl. ¶¶ 182-94, ECF No. 22 (FAC); *see also* Stipulated Dismissal, ECF No. 79 (voluntarily dismissing second and third causes of action under Fed. R. Civ. P. 41(a)(1)(A)(ii)); Order, ECF No. 80 (court endorsed order of stipulated dismissal).<sup>3</sup>

The lone claim remaining in this case, then, is Plaintiffs’ challenge to the provisions of the Final Rule which require participating establishments’ employees to sort pigs before presenting them for federal ante-mortem inspection. *See* FAC ¶¶ 174-81. Plaintiffs assert variously that the new sorting rules violate the APA because they are contrary to the FMIA and the HMSA, because USDA did not consider record evidence, and because USDA did not adequately state its reasons for promulgating these rules. The statutory and regulatory background to this claim is described below.

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<sup>2</sup> The Final Rule also included two mandatory provisions that apply to all swine slaughter establishments: they must develop and implement sanitary dressing and microbiological sampling plans. *See* 84 Fed. Reg. at 52322-33. These universal requirements are not at issue in this case.

<sup>3</sup> Rather than voluntarily dismiss these claims, Plaintiffs had initially sought to stay them indefinitely. *See* Pls.’ Mot. to Stay, ECF No. 70. Following motion practice and a hearing on their motion to stay, however, Plaintiffs elected to proceed with a stipulated dismissal without prejudice.



## I. Statutory Background

Congress found that it is in the public interest to protect consumers' health by "assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 602. Based on this finding, Congress at the beginning of the twentieth century first enacted the FMIA, and directed the Secretary of Agriculture to have FSIS inspectors make "an examination and inspection of all amenable species before they shall be allowed to enter" any U.S. establishment that slaughters livestock for food products that are used in commerce. *Id.* § 603(a). Any animals showing symptoms of disease are required to be set apart and slaughtered separately from the other animals. *Id.* This process is called ante-mortem inspection and, like the remainder of the FMIA, it applies to swine slaughter establishments. *See id.* § 601(j), (w)(1).

Although not at issue in this case, the FMIA also requires federal inspectors to make "a post mortem examination and inspection of the carcasses and parts thereof of all amenable species" prepared at any U.S. establishment that slaughters livestock for human consumption. *Id.* § 604. Any carcasses and parts that may be harmful to human health are removed and condemned so they do not enter the food supply. *Id.* §§ 601(m), 604.

Consistent with these provisions, the FMIA requires the Secretary to appoint inspectors to examine all livestock covered by the Act. *Id.* § 621. The inspectors likewise examine the "sanitary conditions" of all slaughter establishments that handle these livestock. *Id.* So that USDA could implement the FMIA, Congress authorized the Secretary to "make such rules and regulations as are necessary for [its] efficient execution." *Id.* Finally, the FMIA incorporates the HMSA, *see id.* §§ 603(b), 610(b), which says that "[n]o method of slaughtering or handling in connection with slaughtering shall be deemed to comply with the public policy of the United States unless it is humane," *see* 7 U.S.C. § 1902.

## II. Regulatory Background

USDA is responsible for implementing the FMIA and for carrying out its mission of protecting consumer health and welfare. *See* 9 C.F.R. § 300.2(b)(1); *see also Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 456 (2012). To do so, USDA has promulgated a series of regulations that govern ante-

and post-mortem inspections at swine slaughter establishments. *See, e.g.*, 9 C.F.R. pts. 309, 310; USDA, *Swine Post-Mortem Inspection Procedures and Staffing Standards*, 50 Fed. Reg. 19900 (May 13, 1985); USDA, *Cattle & Swine Post-Mortem Inspection Procedures and Staffing Standards*, 47 Fed. Reg. 33673 (Aug. 4, 1982); *see also* USDA, *Revision Pursuant to Wholesome Meat Act*, 35 Fed. Reg. 15552, 15563-66 (Oct. 3, 1970). USDA has also issued directives that further detail the inspection processes, including FSIS Directive 6100.1, which concerns ante-mortem inspection of livestock. *See* USDA, FSIS Directive 6100.1, Ante-mortem Livestock Inspection, AR100700-17. These regulations have historically promoted the efficiency of USDA inspections and slaughterhouse operations. *See* 50 Fed. Reg. at 19901; 47 Fed. Reg. at 33673.

#### **A. The Traditional Inspection System**

USDA's 2019 Final Rule allows qualifying swine establishments, if they so choose, to operate under a new inspection system in lieu of the traditional system. Under the traditional inspection system, federal inspectors conduct ante-mortem inspections of all livestock offered for slaughter. *See* 9 C.F.R. § 309.1; USDA, *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4780, 4783 (Feb. 1, 2018) (Proposed Rule). Any animals showing visible signs of disease or other condemnable conditions must be set apart for slaughter separately. *See* 9 C.F.R. § 309.2; 83 Fed. Reg. at 4783. In practice, however, under the traditional inspection system, most market hog slaughter establishments voluntarily segregate animals and set apart those showing visible adverse signs before federal inspection occurs. 83 Fed. Reg. at 4783. Establishments that do so must document their segregation procedures, and, after establishment personnel finish segregating, the federal inspectors inspect each animal offered for slaughter. *See id.* Federal inspectors also must observe the establishment's voluntary segregation procedures at least once per month. FSIS Directive 6100.1, § XI(B)(5), AR100708.

As for post-mortem inspection, under the traditional system, federal inspectors must inspect each hog in three separate parts: head, viscera, and carcass. 9 C.F.R. § 310.1(b)(3); 83 Fed. Reg. at 4783. Federal inspectors identify localized defects that are correctable through trimming, and they direct establishment employees to remove these defects. 83 Fed. Reg. at 4783. Federal inspectors

also look for signs of disease or contamination by performing incisions and palpations, and they do “organoleptic inspections,” which rely on sight, smell, and touch. *Id.* Under the traditional system’s post-mortem inspection, establishment employees do no pre-inspection sorting, either to identify and remove correctable defects, or to flag carcasses or parts for a federal inspector’s condemnation decision. *Id.* Thus, under the traditional inspection system, up to seven federal inspectors must be assigned per line, per shift, in large establishments. *Id.*

### **B. A New Approach to Food Safety at Meat and Poultry Establishments**

In 1996, USDA launched an initiative designed to address the public health risks associated with foodborne pathogens not detectable through traditional organoleptic inspection. *See* 83 Fed. Reg. at 4787; USDA, *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems*, 61 Fed. Reg. 38806, 38807 (July 25, 1996). USDA first published a final rule in 1996 that required establishments to develop a system of preventive controls designed to reduce pathogens and the foodborne illnesses that they cause. *See* 61 Fed. Reg. at 38806. The 1996 initiative marked a paradigm shift in USDA’s approach to fulfilling its statutory mandate; it put greater onus on establishments to ensure product safety and gave them flexibility to determine the best way to comply with USDA’s food safety program. *See id.* at 38808; *see also* 83 Fed. Reg. at 4787. To align with the new philosophy and to fulfill its food safety mission, USDA recognized that it must continue to adjust its approach to slaughter inspection and that it must continue to clarify the division of responsibility. 61 Fed. Reg. at 38808.

In 1997, USDA adjusted its approach to slaughter inspection by developing the HACCP-Based Inspection Models Project (the HIMP Pilot Project). *See* USDA, *HACCP-Based Meat and Poultry Inspection Concepts*, 62 Fed. Reg. 31553 (June 10, 1997). USDA used the HIMP Pilot Project to design and test new inspection models in five volunteer swine slaughter establishments. *See id.*; 84 Fed. Reg. at 52302.<sup>4</sup> USDA sought to correct something it saw as a “major problem”: slaughter establishments were relying on USDA employees to sort acceptable products from unacceptable products and thus

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<sup>4</sup> Twenty-five poultry slaughter establishments also participated in the HIMP Pilot Project. 84 Fed. Reg. at 52302.

“ha[d] no mandate or incentive to remove carcasses and parts” before inspection. 62 Fed. Reg. at 31555. USDA explained that, under the traditional inspection system, the government was expending resources “inappropriately and inefficiently” to “take on the industry’s responsibility for finding defects, identifying corrective actions, and solving production control problems.” *Id.*

Because USDA was allocating its resources inefficiently, there was “[a] much more significant problem with” the traditional inspection system: it did not allow USDA “to allocate resources according to public health risk.” *Id.* Indeed, the traditional system was designed when animal diseases detectable by organoleptic inspection were more prevalent. *Id.* USDA explained that this has changed because of significant advances in disease control and because livestock are being slaughtered at younger ages. *Id.* Thus, the systems in the HIMP Pilot Project were tested with the goals of (1) improving food safety, (2) increasing inspection effectiveness, (3) reducing the risk of foodborne illness, (4) promoting industry innovation, and (5) using USDA’s resources more efficiently. *See* 83 Fed. Reg. at 4787.

In 1997, the HIMP Pilot Project was first rolled out, and it involved changes to both the ante- and post-mortem inspection processes in the five swine slaughter establishments that eventually joined the pilot project.<sup>5</sup> *Id.* at 4787-88. Relevant here, the HIMP ante-mortem process is similar to the voluntary segregation system that many market hog establishments are using already. *Id.* That is, establishment employees sort animals before presenting them to federal inspectors, disposing of any animals that are deceased or suspected of having certain disorders. *Id.* at 4788. Following that sorting by establishment employees, federal inspectors examine all live animals offered for slaughter, and the inspectors direct the employees to remove any additional animals suspected of having certain diseases. *Id.* FSIS public health veterinarians (PHVs) examine all animals removed (but not condemned) by establishment employees and by federal inspectors to determine whether those animals may be offered

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<sup>5</sup> USDA originally proposed a HIMP model that did not require federal inspectors to examine each carcass. *Am. Fed’n of Gov’t Emps., AFL-CIO v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000) (*AFGE I*). The D.C. Circuit found this approach was inconsistent with the FMIA. *Id.* In response, USDA modified HIMP, and the D.C. Circuit held that the revised HIMP Pilot Project complied with the FMIA because it requires federal inspectors to examine each hog head, carcass, and viscera. *Am. Fed’n of Gov’t Emps., AFL-CIO v. Veneman*, 284 F.3d 125, 130-31 (D.C. Cir. 2002) (*AFGE II*).

for slaughter or condemned before slaughter. *Id.* FSIS inspectors also observe establishment sorting procedures at least twice per shift. *Id.*

In 2014, USDA analyzed comprehensive data from establishments that participated in the HIMP Pilot Project from 2006 to 2013 and published a HIMP Report. *See id.* at 4788-89. The HIMP Report compared the performance of the HIMP participants with comparable establishments operating under the traditional inspection system. *Id.* at 4789. Overall, USDA found that federal inspectors performed more offline verification activities at the HIMP Project Pilot participants, and those participants had no more incidents of food-safety defects—and in some cases had fewer food-safety defects—than establishments operating under the traditional system. *Id.* at 4789-90. USDA also published a peer-reviewed risk assessment; the data suggest that as federal inspectors increase certain offline procedures, the prevalence of *Salmonella* in market hog carcasses decreases. *Id.* at 4791.

USDA also analyzed humane handling data collected by participating HIMP establishments from 2013 through 2015. Based on its Humane Activities Tracking System (HATS), USDA “found that FSIS inspectors spent more time verifying that specific humane handling and slaughter requirements were met in HIMP market hog establishments than in non-HIMP market hog establishments.” *Id.* at 4790. USDA also found that “FSIS inspectors documented fewer humane handling NRs [noncompliance reports] in HIMP market hog establishments than in non-HIMP market hog establishments.” *Id.* Overall, USDA concluded that “[t]he data demonstrate that HIMP establishments have higher compliance with humane handling regulations than non-HIMP establishments, and that increased offline inspection may improve compliance with the HMSA.” *Id.* at 4791.

### **C. Modernizing Swine Slaughter Inspection: The Proposed and Final Rules for the New Swine Slaughter Inspection System**

Based on the results of the HIMP Pilot Project, in early 2018, USDA published a notice of proposed rulemaking. 83 Fed. Reg. at 4780. The Proposed Rule set out to amend the system for inspecting market hogs that are offered for slaughter by allowing qualifying establishments to operate under a new optional inspection system, the New Swine Slaughter Inspection System or NSIS. *Id.*

The key elements of NSIS include the three features tested during the HIMP Pilot Project: (1) it requires establishment employees to perform ante- and post-mortem sorting activities before federal ante-mortem and post-mortem inspection; (2) it requires establishment employees to trim and identify defects on animal carcasses and parts before post-mortem inspection by FSIS inspectors, reducing the number of online FSIS inspectors to a maximum of three per line and enabling USDA to shift some resources from online inspection to offline inspection activities; and (3) it revokes maximum line speeds and allows establishments to set their own speeds based on their ability to maintain process control. *Id.* at 4781.

In October 2019, USDA published the Final Rule, effective December 2, 2019. 84 Fed. Reg. 52300. The Final Rule adopted the three key elements set out in the Proposed Rule. *Id.*

Because NSIS is optional, to assess the Rule's economic impacts, USDA considered how many qualifying establishments might opt in to the new system. *See id.* at 52322. It predicted that, due to economic constraints, not every market hog establishment would do so. *Id.* Forty of these establishments existed in 2016 (including the five HIMP Pilot Project participants), but USDA could not know how many of those would ultimately opt in. *See id.* In fact, USDA raised multiple potential adoption scenarios, including that only the five HIMP Pilot Project participants would opt in to NSIS. *Id.* at 52339.

### **III. This Case**

Plaintiffs filed this action on December 18, 2019, and amended their Complaint on February 18, 2020. *See* Compl., ECF No. 1; FAC, ECF No. 22. As noted above, Plaintiffs initially asserted three causes of action, but have since narrowed this case to proceed solely on their first cause of action. *See* Stipulated Dismissal, ECF No. 79; Order, ECF No. 80. In their remaining cause of action, Plaintiffs allege that the Final Rule's pre-inspection sorting procedures and ante-mortem inspection provisions are inconsistent with the FMIA and the HMSA and are arbitrary and capricious and an abuse of discretion in violation of the APA, and that those aspects of the Final Rule should therefore be set aside. *See* FAC ¶¶ 174-81.

As this Court is aware, Defendants previously moved to dismiss this action for lack of standing. *See* Mot. to Dismiss, ECF No. 25; Mem. of Law in Supp. of Mot. to Dismiss, ECF No. 26. On June 28, 2021, after concluding that Plaintiffs had sufficiently alleged standing at the pleading stage, this Court denied the motion to dismiss. *See* Decision and Order, ECF No. 50. Defendants thereafter produced the administrative record. *See* ECF Nos. 58-60, 65. Plaintiffs filed their Motion for Summary Judgment on August 22, 2022. ECF No. 86.

### LEGAL STANDARD

“Where a party seeks review of agency action under the APA, ‘the entire case on review is a question of law.’” *New York Legal Assistance Grp. v. DeVos*, 527 F. Supp. 3d 593, 599 (S.D.N.Y. 2021) (quoting *Seife v. U.S. Dep’t of Health & Hum. Servs.*, 440 F. Supp. 3d 254, 271 (S.D.N.Y. 2020)). “While the usual summary judgment standard under Federal Rule of Civil Procedure 56 does not apply in such cases, summary judgment [as a remedy] nonetheless is ‘generally appropriate’ because courts ‘address legal questions in deciding whether the agency acted arbitrarily, capriciously or in some other way that violates’ the APA.” *Id.* (alteration in original) (citation omitted). “After the agency resolves factual issues and develops the administrative record, the district court ‘determine[s] whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.’” *New York v. U.S. Dep’t of Health & Hum. Servs.*, 414 F. Supp. 3d 475, 517 (S.D.N.Y. 2019) (alteration in original) (quoting *Roberts v. United States*, 883 F. Supp. 2d 56, 62 (D.D.C. 2012)).

In reviewing agency action, including rulemaking, a court cannot “substitute its judgment for that of the agency,” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), and should sustain the agency action if the agency “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action” and identified a “rational connection between the facts found and the choice made,” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). The standard of review is “highly deferential,” *see Brodsky v. U.S. Nuclear Regul. Comm’n*, 704 F.3d 113, 119 (2d Cir. 2013), and a court’s scope of review “is narrow because a court must be reluctant to reverse results supported by a weight of considered and carefully articulated expert opinion,” *Cnty. of Westchester v. U.S. Dep’t of Hous. & Urb. Dev.*, 802 F.3d 413, 431 (2d Cir. 2015).



(internal quotation marks omitted). An agency rule will thus only be set aside if “the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Waterkeeper All., Inc. v. EPA*, 399 F.3d 486, 498 (2d Cir. 2005) (quoting *State Farm*, 463 U.S. at 43).

### **ARGUMENT**

Nearly all of Plaintiffs’ contentions in this case rest on the flawed premise that under the New Swine Slaughter Inspection System set forth in the Final Rule, establishment employees, and not FSIS inspectors, now conduct the ante-mortem inspections required by the FMIA. But that assumption is simply incorrect. Under NSIS, federal inspectors continue to perform an ante-mortem examination of each and every animal that an establishment presents for slaughter and only animals which FSIS inspectors have passed for slaughter may be prepared and presented for post-mortem inspection. The Final Rule does obligate establishments to perform segregation and sorting tasks, but those occur *before* the mandatory USDA ante-mortem inspections occur. Plaintiffs appear to believe that these sorting activities by establishment employees are a *replacement* for USDA inspection, but that is simply an incorrect reading of the Final Rule.

Owing principally to this flawed understanding of the Final Rule, each of Plaintiffs’ APA legal theories lacks merit. First, the Final Rule does not violate the FMIA and HMSA as Plaintiffs erroneously contend. Their theory rests on the flawed assumption that establishment employees are conducting “inspections” as set forth in the FMIA. But that is incorrect: establishment employees operating under NSIS merely perform *pre*-inspection sorting activities, and a USDA federal inspector continues to inspect each and every animal presented for slaughter. There is no inconsistency with the FMIA and HMSA.

Second, USDA did not improperly “delegate” its own inspection obligations to establishment employees. Again, under NSIS, a FSIS inspector—not an establishment employee as Plaintiffs



mistakenly believe—inspects every market hog that an establishment presents for slaughter, just as the FMIA requires.

Third, the ante-mortem inspection provisions of the Final Rule are not arbitrary and capricious or an abuse of discretion. Contrary to Plaintiffs’ contentions, USDA carefully considered the record evidence, including the accumulated data from the HIMP Pilot Project, and reasonably concluded that adopting NSIS would not increase inhumane handling. Meanwhile, Plaintiffs’ premise that USDA refused to consider evidence of supposedly inadequate inspection training for establishment employees is misplaced; again, FSIS inspectors—not establishment employees—remain responsible for ante-mortem inspections, and USDA thus reasonably concluded that there is no need for the sort of rigorous employee training Plaintiffs demand. Plaintiffs’ assertion that the Final Rule limits USDA’s capacity to detect humane handling violations is likewise based on a misunderstanding of employees’ roles, and is contradicted by evidence gathered from the HIMP Pilot Project. Contrary to what Plaintiffs maintain, USDA is not outsourcing humane handling detection duties to establishment employees. Finally, USDA did not depart from prior ante-mortem inspection practice as Plaintiffs contend, and in any event adequately explained its reasons for adopting NSIS in the Final Rule.

In promulgating the ante-mortem inspection protocols of NSIS, USDA plainly “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Waterkeeper Alliance*, 399 F.3d at 498 (citation omitted). Because the ante-mortem inspection provisions of the Final Rule do not violate the APA, USDA is entitled to summary judgment.

#### **I. The Final Rule is consistent with the FMIA and the HMSA.**

Plaintiffs’ opening contention is that the Final Rule delegates inspection duties from FSIS inspectors to establishment employees. Pls.’ Mot. 15. But that contention is based on a fundamental misreading of the Rule. While establishment employees do perform pre-inspection sorting, those tasks do not *replace* federal inspection; instead, pre-inspection sorting is an additional step *prior to* federal inspection required by the FMIA. 84 Fed. Reg. at 52311. Any hogs that establishment employees

regard as potentially fit for slaughter are examined by a federal inspector or public health veterinarian, as the FMIA requires. And if a federal public health veterinarian finds that any swine “show symptoms of disease” during ante-mortem inspection, such swine are “set apart and slaughtered separately,” as the FMIA also requires. 21 U.S.C. § 603(a). Plaintiffs’ claim that USDA has acted contrary to the FMIA is therefore meritless.

NSIS’s pre-inspection process by establishment personnel is by no means new. “FSIS has allowed establishments operating under traditional inspection to voluntarily implement” virtually identical pre-inspection sorting procedures “since at least the 1980s,” and most market hog establishments did so long before USDA adopted the Final Rule. 84 Fed. Reg. at 52311. As explained below, these sorting procedures comport with § 603(a) because—after the initial sorting—“FSIS inspectors still conduct 100 percent ante-mortem inspection,” *id.* at 52312.

Section 603(a) requires an “examination and inspection” by federal inspectors of all market hogs prior to slaughter. 21 U.S.C. § 603(a). While Plaintiffs believe the Final Rule “impermissibly delegat[es] inspection duties to [] slaughterhouse employees,” Pls.’ Mot. 15, what the Rule in fact requires of those employees is “to sort market hogs and remove for disposal animals unfit for slaughter *before* they are presented to FSIS PHVs for inspection and final disposition,” 83 Fed. Reg. at 4792 (emphasis added). Thereafter, *FSIS inspectors* would inspect “*all* animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion.” 84 Fed. Reg. at 52312 (emphasis added); *see also* 83 Fed. Reg. at 4788; AR100707 (FSIS Directive 6100.1 providing that, for all animals deemed normal by an establishment, federal inspectors examine all animals “while the animals are ‘at rest,’” and then “[s]elect 5 to 10 percent of all animals that the establishment presents for ante-mortem inspection from several lots and observe [them] in motion” (quoting 9 C.F.R. § 309.1(a))).<sup>6</sup> When performing the ante-mortem inspection, the federal inspector is to assess “[t]he overall condition of each animal, including the head, with attention to the eyes, the legs, and the body

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<sup>6</sup> Plaintiffs are further incorrect when they assert that the Final Rule “limits FSIS inspectors to examining only ‘five to ten percent of those animals in motion.’” Pls.’ Mot. 15 (quoting AR100263). The five-to-ten-percent figure is a floor, not a ceiling, on the number of swine in motion that FSIS inspectors can examine. *See* 84 Fed. Reg. at 52312; AR100707.

of the animal”; “[t]he degree of alertness, mobility, and breathing”; and “[w]hether there are any unusual swellings or any other abnormalities.” AR100705. Any swine that the inspector determines to be “abnormal” are moved to a “U.S. Suspect” pen, AR100707 (quoting 9 C.F.R. § 307.2(a)), while swine “found to be healthy on ante-mortem inspection” may proceed toward slaughter, AR100703. The inspector must keep track of the number of swine being inspected and “verify that the number of [swine] slaughtered (during a slaughter shift) is no more than the number of [swine] that have passed ante-mortem inspection.” AR100704. There is no merit to Plaintiffs’ assertion that USDA has “delegate[d] ante-mortem inspection authority to slaughterhouse employees.” Pls.’ Mot. 13.

Indeed, when it promulgated the Final Rule, USDA responded to comments which suffered from the same misunderstanding Plaintiffs have. In response to objections that it was “privatizing” inspection, USDA was clear: “The new inspection system will not eliminate FSIS inspection. NSIS simply requires establishments to take additional steps *before* FSIS inspection to ensure that their products are safe and wholesome.” 84 Fed. Reg. at 52311. Thus, under the Final Rule, and contrary to Plaintiffs’ claim that USDA has “delegated” inspection duties to private employees, USDA “will continue to conduct ante-mortem inspection.” *Id.*

That is precisely the conclusion reached recently by the California district court in *Center for Food Safety v. Vilsack (CFS)*, No. 20-cv-00256-JSW, 2022 WL 4793438 (N.D. Cal. Sept. 30, 2022). Rejecting the plaintiffs’ argument that federal inspection had been “replaced” by establishment employees, the court found that “[u]nder NSIS, federal inspectors still inspect each animal before it is slaughtered for meat.” *CFS*, 2022 WL 4793438 at \*9. Because “federal inspectors still inspect the animals ‘before they shall be allowed to enter into any slaughtering . . . establishment, in which they are to be slaughtered,’” the court concluded, correctly, that “the pre-inspection sorting process [conducted by establishment employees] does not replace federal inspection.” *Id.* (quoting 21 U.S.C. § 603(a)). Plaintiffs therefore have it exactly backwards when they assert that “[t]he [Final] Rule does

not allow FSIS inspectors to undertake inspection,” Pls.’ Mot. 16—there is no such prohibition in the Final Rule and Plaintiffs unsurprisingly point to none.<sup>7</sup>

Plaintiffs also argue that federal inspection of five to ten percent of animals while in motion somehow violates the FMIA. Pls.’ Mot. 15. Again, the federal in-motion inspections occur *in addition to* federal inspections of *all* animals while they are at rest. Insofar as Plaintiffs are contending that the *only* federal inspections are of five to ten percent of the animals while in motion, Plaintiffs are again misreading the Final Rule and ignoring that federal inspectors inspect *all* animals which are presented for slaughter while those animals are at rest. *See* Pls.’ Mot. 15 (“Rather than inspecting all animals as required by Congress, under the new Rule, FSIS inspectors merely observe plant employees’ sorting activities ‘once per month.’” (quoting AR100263)).

If Plaintiffs are instead arguing that the FMIA requires inspection of more than five to ten percent of animals while those animals are in motion, they fail to point to any provision of that statute which so mandates. That is not surprising because the FMIA does not impose any requirement that USDA inspect a given quantum of animals in motion, or even that it inspect animals in motion at all. Rather, § 603(a) states only that FSIS inspectors are required to make “an examination and inspection” before market hogs are “allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce.” 21 U.S.C. § 603(a); *CFS*, 2022 WL 4793438 at \*10 (“[Section 603(a)] does not require all swine to be examined at rest *and in motion*.” (emphasis added)).

The federal inspections under NSIS, which entail an examination of “[t]he overall condition of each animal, including the head, with attention to the eyes, the legs, and the body of the animal”; “[t]he degree of alertness, mobility, and breathing”; and “[w]hether there are any unusual swellings or

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<sup>7</sup> Plaintiffs also assert that FSIS inspectors “merely observe” establishment employees’ sorting activities on a monthly basis. Pls.’ Mot. 15. As explained above, that is a *supplement* to FSIS personnel’s actual inspection of every animal offered for slaughter, and not a *substitute* for those inspections, as Plaintiffs appear to believe. Plaintiffs’ reliance on *AFGE I* for the proposition that “not every observation amounts to an inspection” thus entirely misses the mark. 215 F.3d at 11. FSIS inspectors are not, as Plaintiffs maintain, merely observing, but are actually personally inspecting every animal presented for slaughter, just as § 603(a) contemplates.

any other abnormalities” unquestionably satisfy this requirement. AR100705; *cf. AFGE II*, 284 F.3d at 130 (reaching similar conclusion in the context of post-mortem inspection under 21 U.S.C. § 604). In any event, nothing in the Final Rule precludes FSIS inspectors from electing to examine more than ten percent of the animals while in motion, should they find that additional measure of scrutiny warranted or necessary. *See* AR100707.<sup>8</sup>

## II. The Final Rule is not an unlawful delegation to an outside party.

Plaintiffs’ separate but related argument that the Final Rule “constitutes a delegation to an outside party without affirmative congressional authorization,” Pls.’ Mot. 22, likewise fails, as does their virtually identical argument that such a delegation is “not in accordance with” the FMIA and the HMSA, Pls.’ Mot. at 24-25. Consistent with the FMIA and the HMSA, FSIS inspectors—not third parties—continue to conduct ante-mortem inspection of every animal, and USDA therefore is not “ceding inspection authority over to the very industry it purports to regulate,” as Plaintiffs errantly believe. Pls.’ Mot. 23, 25.

USDA agrees that Congress was clear in the FMIA that the “inspectors” who are to conduct the “examination and inspection” of all hogs presented for slaughter under 21 U.S.C. § 603 must be

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<sup>8</sup> As just explained, Plaintiffs’ argument that the Final Rule is inconsistent with the FMIA and HMSA rests on an erroneous reading, and their reliance on the *Chevron* framework of analysis is likewise misplaced. Indeed, USDA agrees with Plaintiffs that Congress has “directly spoken to the precise question at issue.” *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). That is—and contrary to Plaintiffs’ misunderstanding—Congress has required that all hogs presented for slaughter be “examin[ed] and inspect[ed]” by FSIS inspectors. 21 U.S.C. § 603(a). As explained above, the Final Rule contemplates, and in fact requires, just that. If the *Chevron* analysis has any function, it is to demonstrate that the Final Rule is wholly consistent with § 603(a) and therefore permissible under the statute.

Even if there were a basis to proceed to the second step of the *Chevron* analysis, Plaintiffs never explain why the Final Rule is allegedly not a “permissible construction of the statute.” *Chevron*, 467 U.S. at 843. Indeed, their entire argument is tainted by their erroneous premise. For example, they contend that the Final Rule “cedes inspection authority to [the] slaughterhouses,” Pls.’ Mot. 18, but as explained above, USDA personnel continue to perform inspections of all market hogs. USDA has not, as Plaintiffs maintain, burdened “slaughterhouse employees with the task of ante-mortem inspection in addition to their normal duties,” *id.* at 18, or “hand[ed] over the important task of ante-mortem inspection to industry,” *id.* at 22. It is not USDA that has adopted an impermissible reading of the FMIA or the HMSA as Plaintiffs argue, but rather Plaintiffs who have misread the Final Rule. No *Chevron* step two analysis is required here.

agency personnel, not third parties to which USDA delegates that duty. *See AFGE I*, 215 F.3d at 11 & n.2 (citing 21 U.S.C. § 453(k)). For that reason, as explained above, the Final Rule obligates federal inspectors—*i.e.*, USDA personnel and not third parties—to “inspect every market hog offered for slaughter.” 84 Fed. Reg. at 52312. The slew of cases Plaintiffs cite delineating the permissibility of agency delegations of authority is therefore wholly inapposite. Plaintiffs are simply wrong when they assert that “the vast majority of ante-mortem inspection will be conducted by plant employees.” Pls.’ Mot. 24. Instead, in actuality, “FSIS inspectors inspect every market hog offered for slaughter.” 84 Fed. Reg. at 52312. There has been no delegation of USDA’s inspection authority or inspection obligation here, and there is therefore no need to adjudicate whether Congress authorized any such delegation.

**III. The ante-mortem inspection provisions of the Final Rule are not arbitrary and capricious or an abuse of discretion.**

Contrary to Plaintiffs’ contentions that the Final Rule violates the APA, USDA considered all relevant record evidence when it adopted NSIS in the Final Rule and thoroughly explained its reasons for acting. USDA reasonably concluded that the ante-mortem inspection provisions of the Final Rule would not have an adverse effect on humane handling. It further provided adequate responses to those who commented on the Proposed Rule with humane handling concerns. Finally, NSIS is not a “departure from longstanding agency policy,” as Plaintiffs contend, Pls.’ Mot. 26, and USDA therefore faced no heightened standard of explaining its reasons for adopting the Final Rule. Even so, USDA plainly offered more than sufficient explanation for NSIS to withstand scrutiny under the APA. As detailed below, Plaintiffs’ challenge under the APA fails, and USDA is entitled to summary judgment.

**A. USDA considered all relevant record evidence and concluded that the Final Rule would not have an adverse effect on humane handling.**

Plaintiffs first contend that USDA ignored supposed evidence that NSIS would increase inhumane handling of market hogs. According to Plaintiffs, the HIMP Report “resoundingly demonstrates an *increase* in the inhumane handling of pigs” within establishments that participated in

the HIMP Pilot Project. Pls.’ Mot. 27. Plaintiffs argue that USDA therefore failed to consider that adopting the Final Rule would lead to increased inhumane handling of pigs, and the Rule should thus be set aside. Pls.’ Mot. 27. But Plaintiffs’ allegations that USDA failed to consider the humane handling impact of the Final Rule are belied by the record.

Plaintiffs place much emphasis on the fact that the HIMP Report did not focus on humane handling concerns. *See* Pls.’ Mot. 28-29. But whether the HIMP Report addressed humane handling is beside the point, since Plaintiffs in this lawsuit challenge not the HIMP Report but the ante-mortem aspects of the Final Rule. Rather, the relevant question is whether USDA, in promulgating the Final Rule or in response to comments about the humane handling impacts of the Proposed Rule, adequately considered humane handling. The record shows that USDA did so.

At the outset, in the Proposed Rule, USDA detailed the manner in which its inspectors verified that HIMP-participating establishment complied with the humane handling requirements of the HMSA. 83 Fed. Reg. at 4790-91. The data USDA had collected showed that FSIS inspectors were able to devote more time to verifying humane handling in HIMP establishments than in non-participating establishments, and the data further “demonstrate[d] that HIMP establishments have higher compliance with humane handling regulations than non-HIMP establishments, and that increased offline inspection may improve compliance with the HMSA.” *Id.* at 4791.

That USDA took animal welfare and humane handling concerns into account is further evident in the Final Rule from its consistent focus on anticipated improvements to animal welfare: “FSIS expects that the new inspection system will improve animal welfare and compliance with the HMSA because more FSIS resources will be available to verify the humane handling of animals.” 84 Fed. Reg. at 52300; *see also, e.g., id.* at 52315 (“FSIS was able to conduct more offline humane handling verification tasks under HIMP as compared to traditional inspection.”), 52336 (“Additionally, the NSIS increases the Agency’s ability to conduct more process and product verification and to increase monitoring of humane handling procedures, which is expected to improve animal welfare.”). USDA reviewed the data from HIMP participants in its Humane Activity Tracking System, and found that under HIMP, which bears substantial similarities to NSIS, its inspectors were able to devote over one



additional hour per shift to “verifying humane handling activities.” *Id.* at 52336. USDA further concluded that the pre-inspection sorting performed by establishment employees under NSIS will permit FSIS inspectors “more time to conduct offline inspection activities” which include “monitoring of humane handling procedures.” *Id.* at 52336.<sup>9</sup> Plaintiffs’ claims that USDA “did not evaluate animal welfare impacts” or that USDA “omitted any reference to impacts on humane handling” are simply false. Pls.’ Mot. 27-28.

Plaintiffs also cite a number of individual non-compliance episodes in HIMP establishments. Pls.’ Mot. 28-29. Plaintiffs’ apparent theory is that USDA failed to consider evidence that instances of inhumane handling were “more likely to go unreported [in HIMP establishments] due to the delegation of ante-mortem inspection duties to slaughterhouse employees.” Pls.’ Mot. 28. As explained above, this argument’s premise—that “ante-mortem inspection duties” had been “delegated” to HIMP establishment employees—is fundamentally flawed. Under the HIMP Pilot Project (just as under the Final Rule), FSIS inspectors conducted all ante-mortem examinations and inspections required by the FMIA.

As for the substance of Plaintiffs’ argument, the simple fact that noncompliance episodes occurred at HIMP-participating establishments does not mean that USDA did not consider humane handling impacts when it promulgated the Final Rule. It therefore does little for Plaintiffs to show that as a historical matter, there were inhumane handling instances at HIMP establishments, without also showing that there were no such instances at non-HIMP establishments.

Furthermore, while Plaintiffs contend that humane handling noncompliance is “more likely to go unreported” at HIMP establishments, Pls.’ Mot. 28, they do not suggest any evidence showing a relatively lower level of noncompliance at non-HIMP establishments. That is, Plaintiffs fail to demonstrate the “more likely” aspect of their own argument. As USDA noted in the Proposed Rule,

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<sup>9</sup> Although related to a different aspect of the Final Rule from the one Plaintiffs challenge, USDA also gave due consideration to comments which raised humane handling concerns about the revocation of maximum line speeds. *See* 84 Fed. Reg. at 52315 (responding to “[c]omments from animal welfare advocacy organizations . . . revoking maximum line speeds for establishments that operate under NSIS will have adverse effects on the humane handling of swine” and “disagree[ing] that revoking line speeds will have a negative effect on animal welfare”).



based on a review of humane handling data from 2013 to 2015, the opposite was true: after “compar[ing] the rate of humane handling NRs issued in HIMP market hog establishments and non-HIMP market hog establishments,” USDA “inspectors documented fewer humane handling NRs in HIMP market hog establishments than in non-HIMP market hog establishments.” 83 Fed. Reg. at 4790. Accordingly, USDA concluded based on the data that “HIMP establishments have higher compliance with humane handling regulations than non-HIMP establishments, and that increased offline inspection may improve compliance with the HMSA.” *Id.* at 4791.

At bottom, Plaintiffs’ cited instances of noncompliance, *see* Pls.’ Mot. 28-29, stand only for the proposition that inhumane handling activities occurred in those comparatively small numbers at HIMP establishments—something that USDA does not deny. Contrary to showing that USDA somehow ignored this evidence, the record instead shows that the agency expressly relied on the incidence of humane handling noncompliance when USDA conducted its rulemaking and determined to expand the HIMP ante-mortem inspection provisions and make them available to all slaughter establishments. *See* 83 Fed. Reg. at 4790-91.

Plaintiffs also focus on a 2015 undercover video investigation of a HIMP establishment conducted by Plaintiff Animal Outlook, and which was the subject of a comment on the Proposed Rule. *See* Pls.’ Mot. 29 (citing AR063771-4079; AR054208-10). But USDA explicitly responded to this investigation in the Final Rule. After expert USDA personnel reviewed the undercover video, they “determined that there was unacceptable rough handling and inappropriate use of a rattle paddle to drive animals.” 84 Fed. Reg. at 52315. Contrary to Plaintiffs’ erroneous statement that “no agency action was taken” in response, Pls.’ Mot. 29, USDA explained that it “took immediate regulatory action against the establishment and required it to respond with acceptable corrective actions to prevent a recurrence,” 84 Fed. Reg. at 52315. Although this particular incident was concededly a humane handling violation, there is nothing to suggest that it was not properly addressed by USDA in the fashion contemplated by its regulations.

Plaintiffs go on to raise concerns over the watchdog reports issued by the USDA Office of Inspector General and the General Accountability Office, but Plaintiffs are incorrect that USDA

“failed to address the concerns raised by OIG and GAO.” Pls.’ Mot. 29. USDA expressly acknowledged the report findings of both agencies. 84 Fed. Reg. at 52306-07. USDA explained that it “addressed OIG’s concerns in the Agency’s responses to the [OIG] audit,” and went on to detail the responsive measures that USDA implemented, including improvements to its ability to track non-compliance reports, supplemental training modules, and the hiring of a Humane Handling Enforcement Coordinator. *Id.* at 52305-6. USDA also responded to GAO’s findings concerning what GAO perceived to be limitations of the HIMP Pilot Project. In response to those perceived limitations, USDA explained, it undertook the data collection and analysis effort that resulted in the HIMP Report. *Id.* at 52306. USDA further acknowledged that while the five HIMP-participating establishments represented a “small sample size,” they also “collectively represent diversity in geography, corporate structure, management styles, product distribution patterns, and other variables” such that they could be viewed collectively as “typical of the broader industry.” *Id.* Plaintiffs flatly ignore these agency responses when they assert, incorrectly, that USDA “failed to address the concerns raised by OIG and GAO.” Pls.’ Mot. 29.

Finally, Plaintiffs’ laundry list of comments submitted by various entities and organizations, *see* Pls.’ Mot. 30—to the extent those comments bear on the ante-mortem provisions of the Final Rule at all—were not “ignored” as Plaintiffs maintain. Again, contrary to Plaintiffs’ conclusory claim that USDA “did not even attempt to address” the variety of concerns raised by these commenters, the Final Rule makes clear that USDA reviewed the comments it received and provided thorough responses explaining why it was reaching the conclusions it did. *See* 84 Fed. Reg. at 52311 (responding to comments on animal welfare); *id.* at 52315 (same); *id.* at 52311-12 (responding to comments asserting that employees will perform FSIS functions); *id.* at 52312-13 (respond to comment asserting inadequate employee training). Plaintiffs’ conclusory assertion to the contrary does not hold up against the record.

**B. USDA did not ignore evidence regarding training of establishment employees, and, in any event, those employees are not tasked with “the same inspection duties” as FSIS inspectors.**

Plaintiffs’ next argument—that USDA ignored evidence that establishment employees lack the training to perform the tasks of FSIS inspectors—again rests on the same erroneous premise as their other arguments. As explained above, establishment employees do not “perform the same inspection duties as FSIS inspectors,” Pls.’ Mot. 31; rather, under the Final Rule, those employees perform sorting activities *prior to* FSIS inspectors conducting the inspections of all market hogs presented for slaughter. Since the duties and responsibilities of FSIS inspectors differ substantially from those of establishment employees, it is hardly surprising that the former undergo more extensive training on various inspection protocols. *See* Pls.’ Mot. 32.

Insofar as Plaintiffs can be understood to argue that USDA did not consider whether training for establishment employees is necessary under the Final Rule, they are mistaken. As the Final Rule shows, USDA received comments from “[s]everal consumer advocacy groups and a public health organization” which “recommended that FSIS establish training for establishment employees performing sorting activities and require sorters to prove proficiency in performing their duties.” 84 Fed. Reg. at 52313. USDA also received comments from the pork processing industry stating that HIMP establishments “have been successful at training employees to sort for food safety and non-food safety defects.” *Id.* USDA further responded in the Final Rule to concerns from commenters that “establishment employees will miss many food safety and [other consumer protection] defects.” *Id.* at 52312.

In response to these competing submissions, USDA determined not to “prescribe[e] specific sorter training or certification.” *Id.* at 52313. USDA explained that it did not share commenters’ adverse concerns about establishment employees because of USDA’s experience under HIMP, and its determination that HIMP establishments have “very low” rates of food-safety defects, visible contamination, and other consumer protection defects. *Id.* at 52312.

Although USDA did not mandate any particular training regimen for establishment employees, USDA has continued to make available a training guide relevant to the sorting duties establishment employees are expected to perform under the Final Rule. As USDA explained, it published a training guide “based on the [same] training that FSIS provides to its online inspection personnel that are responsible for sorting carcasses under the existing inspection systems” in place prior to the Final Rule. *Id.* at 52313. Moreover, USDA veterinarians are available on-site “to discuss [pathological] conditions and [veterinary] terms if an establishment has any questions.” *Id.* Thus, not only is Plaintiffs’ contention that USDA did not address concerns about establishment employees belied by the record, but USDA also “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action,” *State Farm*, 463 U.S. at 43.

In their brief, Plaintiffs also rely on the 2014 affidavits of two FSIS inspectors, and again contend that USDA did not address the concerns contained in them. Pls.’ Mot. 31-32. First, this argument is immaterial to Plaintiffs’ claims because these inspectors’ affidavits focused on an assertedly inadequate level of training for establishment employees engaged in *post-mortem* activities, whereas here Plaintiffs’ remaining claim focuses solely on purported deficiencies in the *ante-mortem* inspection process under the Final Rule. *See* FAC ¶¶ 174-81; Pls.’ Mot. 32-33 (citing AR093416 (asserting that establishment employees “weren’t trained in the proper procedures for inspecting the viscera and incising lymph nodes”) and AR093432 (inspector asserting that employees “don’t know pathology and are easily manipulated into passing carcasses that should realistically be condemned”)). Second, in the Final Rule, USDA *did* consider these very affidavits and the inspectors’ stated concerns, belying Plaintiffs’ blanket assertion that USDA ignored them. *See* 84 Fed. Reg. at 52312 (“A few commenters referenced affidavits from three FSIS inspectors who worked in HIMP establishments who stated that because of excessive line speeds and lack of training, establishment sorters routinely miss many food safety and wholesomeness defects.”).

Meanwhile, the February 2018 comment from a FSIS veterinarian on which Plaintiffs rely, *see* Pls.’ Mot. 32-33, states only that the ante-mortem responsibility to remove unfit animals should “remain within the Agency,” AR020694-95, which, under the Final Rule, it does. FSIS inspectors

preserve full authority to determine, ante-mortem, that an animal should be condemned. *See* 84 Fed. Reg. at 52312 (“If any animals exhibit signs of condemnable conditions, FSIS inspectors direct establishment employees to move the animals to the ‘U.S. Suspect’ pens for final disposition by the FSIS PHV.”).<sup>10</sup>

Finally, Plaintiffs point out that FSIS inspectors, and not establishment employees, are authorized to take enforcement actions for humane handling violations. Pls.’ Mot. 33. It is indisputably true (and set forth in USDA regulations) that only USDA may take a “regulatory control action,” a “withholding action,” or a “suspension” against an establishment. *See* 9 C.F.R. §§ 500.2, 500.3. And Defendants agree that such action can, by definition, only be taken if USDA becomes aware of the underlying noncompliant conduct. There was thus no “evidence” for USDA to “disregard,” as Plaintiffs incorrectly assert. Pls.’ Mot. 33. If Plaintiffs are trying to argue that FSIS inspectors will no longer be present under NSIS—and thus be incapable of observing humane handling violations—USDA has shown that that premise is fundamentally wrong. *See, e.g.*, 84 Fed. Reg. at 52312 (“Under the NSIS, FSIS inspectors will observe establishment employees performing sorting procedures. During this time, FSIS inspectors will verify that animals that are intended to be disposed of are humanely euthanized . . .”). USDA is not turning over all inspection duties to establishments, as Plaintiffs appear to believe. The upshot of Plaintiffs’ argument in this regard is otherwise difficult to discern.

USDA did not “ignore” purported evidence that establishment employees cannot perform the duties of FSIS inspectors because the Final Rule does not task those employees with those duties.

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<sup>10</sup> Plaintiffs also cite a non-compliance report from September 2013 in which a FSIS inspector had to assist establishment employees with a hog that “had become stuck in the east side restrainer.” AR100490; *see* Pls.’ Mot. 33. It is unclear what this episode has to do with USDA’s alleged non-consideration of training for establishment employees’ performance of pre-inspection sorting activities. Plaintiffs in their brief theorize that absent USDA intervention, the employees “would have simply kept processing the suffering animal without taking any corrective measures to prevent other animal [*sic*] from getting stuck in the future.” Pls.’ Mot. 33. But that assertion is entirely speculative and finds no support in the incident report contained in the record. *See* AR100490. Moreover, Plaintiffs’ ultimate argument from this incident that the Final Rule “all but eliminates” ante-mortem inspection by trained USDA personnel is simply incorrect, for the reasons already explained. Pls.’ Mot. 33.

And USDA did adequately consider the specific concerns that Plaintiffs now raise about training for establishment employees. Plaintiffs' employee-training argument provides no basis to set aside the ante-mortem provisions of the Final Rule.

**C. USDA adequately considered whether staffing levels under NSIS would allow it to meet humane handling requirements.**

Plaintiffs contend that an anticipated reduction in USDA staffing under NSIS will “allow inhumane handling violations to go unnoticed and unaddressed.” Pls.' Mot. 34.<sup>11</sup>

*First*, insofar as Plaintiffs attribute this reduction to an asserted “delegation of agency inspection duties to slaughterhouse employees,” they are mistaken, for all of the reasons described above. Pls.' Mot. 34.

*Second*, Plaintiffs acknowledge that in HIMP establishments, FSIS inspectors' time spent verifying humane handling activities *increased* when compared to non-HIMP establishments—from 4.29 hours to 5.33 hours per shift. *See* Pls.' Mot. 34. But, Plaintiffs argue, that increased time spent on humane handling verification is illusory because the agency's Humane Activity Tracking System (HATS) does not break down the types of verification activity by category, and it is thus impossible to determine how much time inspectors spend on ante-mortem humane handling activities. *See* Pls.' Mot. 34-35 (citing AR0100819).

This argument misunderstands the import of the time recorded by FSIS inspectors in HATS. During ante-mortem inspection—and indeed at all times prior to an animal's slaughter and until it has been rendered unconscious—FSIS inspectors are continuously monitoring for humane handling violations, regardless of which particular activity category time is entered in HATS (or whether time is entered at all). AR100820 (“PHVs and other trained [inspection program personnel] are to perform verification of the establishment's humane handling activities during each shift that animals are slaughtered, or when animals are on site, even if it is during a processing only shift.”). Put differently,

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<sup>11</sup> The cited reduction from 365 to 218 full-time USDA employees in swine slaughter inspection is based on agency projections of the number of establishments that will voluntarily opt in to NSIS. *See* 84 Fed. Reg. at 52336.

a FSIS inspector need not enter time in HATS under the “ante-mortem inspection” activity category (or indeed any category at all) in order to monitor establishments’ conduct for humane handling compliance. *See, e.g.,* AR100830-36 (providing guidance for reporting humane handling noncompliance without injury to animals, with injury or distress but not of an egregious nature, and involving treatment of an egregious nature). The fact that FSIS inspectors in HIMP establishments were able to devote additional time to verifying humane handling activities relative to their non-HIMP counterparts only reinforces the efficiency of the ante-mortem inspection process under NSIS, such that inspectors had additional time to devote to these humane handling verification tasks.

In any event, Plaintiffs are incorrect that HATS does not break down time spent by activity category. FSIS inspectors are directed “to accurately and completely report the time that they spend on these [humane handling verification] activities *and to separate that time into nine specific categories.*” AR100818 (emphasis added). Moreover, Plaintiffs have not shown that humane handling verifications in the ante-mortem inspection category are *lower* in HIMP establishments than in non-HIMP establishments. And Plaintiffs point to no minimum quantum of humane handling verifications in the ante-mortem inspection category that any statute or regulation requires USDA to record. Even if the amount of time a FSIS inspector spends on humane handling verification activities in one category has gone down (while going up in others), that does not amount to a violation of the HMSA, as Plaintiffs apparently believe.<sup>12</sup> At bottom, the fact that FSIS inspectors in HIMP establishments recorded more time in HATS across *all* categories is, as USDA concluded, substantial evidence that NSIS will permit the agency to “increase monitoring of humane handling procedures, which is expected to improve animal welfare.” 84 Fed. Reg. at 52336.

Third, USDA did plainly consider that inspection staff were likely to be reduced after NSIS was phased in to participating establishments, since the Final Rule itself includes projections of the

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<sup>12</sup> Furthermore, the activity categories to which FSIS inspectors attribute time in HATS, and the compliance verifications that FSIS inspectors perform for each category, are to some extent overlapping. Thus, compliance verification time that is performed under the “ante-mortem inspection” category might just as correctly be recorded under a different category. *See* AR100824-27 (detailing HATS categories and verification tasks).



staff reductions, *id.* at 52336-37. Even with expectations of reduced inspection staff, however, it was not unreasonable for USDA to adopt NSIS in the Final Rule. That is so because even if the number of overall FSIS inspectors goes down, it remains the case that each and every market hog presented for slaughter undergoes ante-mortem inspection. *Id.* at 52312 (“FSIS inspectors still conduct 100 percent ante-mortem inspection.”). Reductions in staff based on efficiency gains from NSIS are also not unreasonable given the concrete evidence of the outcomes from the HIMP Pilot Project detailed in the HIMP Report. Specifically, USDA found in the HIMP Report that HIMP establishments were “performing as well as comparable large non-HIMP market hog establishments,” “received more off-line food safety related inspection verification checks,” “had higher compliance with Sanitation SOP and HACCP regulations, lower levels of non-food safety defects, equivalent or better *Salmonella* verification testing positive rates than traditional non-HIMP market hog establishments, and lower levels of violative chemical residues.” *Id.* at 52303. These conclusions, coupled with the findings that inspectors at HIMP establishments devoted *more* time to humane handling verifications and “have higher compliance with humane handling regulations than non-HIMP establishments,” 83 Fed. Reg. at 4790-91, show that it was not arbitrary for USDA to create an option for establishments to adopt the inspection protocols rooted in the HIMP Pilot Project. As USDA concluded, “HIMP has been demonstrated to provide public health protection at least equivalent to the traditional inspection system.” 84 Fed. Reg. at 52303.

Insofar as Plaintiffs again rely on the 2013 report by USDA’s Office of Inspector General, *see* Pls.’ Mot. 35 (citing AR054210-12), Defendants have already explained how USDA took measures in response. *See* 84 Fed. Reg. at 52305-06 (citing measures taken in response to the OIG report, including “supplemental training . . . to improve inspectors’ objective observation skills,” the hiring of a “Humane Handling Enforcement Coordinator, who conducts ongoing reviews of relevant NRs, suspensions and Notices of Intended Enforcement,” updating its humane handling directive, and issuing alerts to USDA inspection personnel that help USDA “better identify trends that may warrant an FSIS enforcement action”). The 2013 OIG report does not, as Plaintiffs appear to believe, conclusively demonstrate that USDA is unable to enforce the HMSA. Moreover, contrary to



Plaintiffs' contentions, not only did USDA consider the 2013 OIG Report cited in Plaintiff Animal Legal Defense Fund's comments, but it detailed in the Final Rule the numerous measures it undertook in response to that Report. *Id.* In addressing the concerns OIG identified in its 2013 report, USDA was not limited to increasing the number of inspection personnel at slaughter establishments, as Plaintiffs apparently desire. *See State Farm*, 463 U.S. at 43 (agency decision not arbitrary and capricious if it can be "ascribed to a difference in view").

In sum, it was not arbitrary and capricious for USDA to issue the Final Rule's ante-mortem inspection provisions while simultaneously acknowledging its reasonable expectation that agency inspection personnel headcounts were likely to decrease overall in light of the different staffing approach of NSIS.

**D. USDA acknowledged that it was changing the voluntary swine slaughter inspection system and adequately explained the reasons for the change.**

In their final argument, Plaintiffs claim that USDA's "delegation of ante-mortem inspection duties disregards decades of prior agency regulations and directives emphasizing the importance of *FSIS inspectors* conducting ante-mortem inspection of each and every animal." Pls.' Mot. 36. Again, however, Plaintiffs' fundamental misreading of the Final Rule essentially nullifies this argument. As USDA has explained, the Final Rule does not delegate ante-mortem inspection responsibility to industry employees, and FSIS inspectors continue to inspect "each and every animal" under NSIS. Accordingly, USDA is not "changing position" in the manner that Plaintiffs allege: FSIS inspectors, not establishment employees, will continue to "inspect every market hog offered for slaughter." 84 Fed. Reg. at 52312. Since there has been no policy change in who executes the inspection obligations imposed by the FMIA, USDA had no need to meet a heightened bar for explaining its reasons. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016).

Even reading Plaintiffs' argument charitably, and interpreting them to argue that the inspection of ten percent of pigs while "in motion" is a reversal in policy, their argument nonetheless fails. *See* Pls.' Mot. 37. While FSIS Directive 6100.1 does indicate that FSIS inspectors are to "observ[e] all livestock" while "[i]n motion," Plaintiffs neglect to mention that this requirement of the Directive on

its face does not apply at “establishments that have voluntary segregation procedures described in Section XI.” AR100705. In the referenced Section XI of Directive 6100.1, USDA makes clear that when an establishment “voluntarily segregates animals . . . i.e., segregating those animals showing signs of abnormalities or diseases from healthy animals,” USDA swine inspectors are not required to observe all animals in motion, but are instead to “[s]elect 5 to 10 percent of all animals that the establishment presents for ante-mortem inspection from several lots and observe in motion.” AR100707. That policy, which existed under both the traditional inspection system and the HIMP Pilot Project, is the same one that exists under the Final Rule for establishments that opt into NSIS. *See* 84 Fed. Reg. at 52312 (“FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion.”). And those establishments that remained under the traditional inspection system have largely chosen to adopt voluntary segregation procedures. *See* 83 Fed. Reg. at 4783 (“Most establishments under traditional inspection that slaughter only market hogs voluntarily segregate animals that show signs of diseases or conditions from healthy animals before the Agency performs ante-mortem inspection.”). Meanwhile, the policy concerning inspection of hogs in motion that is reflected in the Final Rule is the same as the policy for establishments that participated in the HIMP Pilot Project. *See Id.* at 4788 (“Under HIMP, FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion.”). Plaintiffs are thus flatly incorrect when they contend that for “more than 50 years,” USDA inspected “all animals both at rest and in motion.” Pls.’ Mot. 38. It has long been the case, since at least the 1980s, that FSIS inspectors, just as they do under the Final Rule, have inspected a minimum of five to ten percent of animals in motion (while also inspecting all animals while at rest). Even reading Plaintiffs to argue this specific point, they again rest their argument on a flawed factual premise.

Although Plaintiffs do not argue as much, it is true that the implementation of NSIS is a “change” in agency policy in the sense that all market hog slaughter establishments can now opt into a system that was previously available only to HIMP participants. That USDA made that new system available to establishments does not mean that it “overruled its previous position” in the manner

Plaintiffs describe, and there is accordingly no heightened obligation to explain such a departure. *Encino Motorcars*, 579 U.S. at 222.

However, even if Plaintiffs might attempt to broaden their supposed “policy reversal” argument to encompass the entirety of NSIS,<sup>13</sup> Plaintiffs cannot seriously contend that USDA did not “display awareness that it *is* changing position” and “show that there are good reasons for the new policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). In the Final Rule, USDA made clear that it was “establishing an optional new inspection system for market hog slaughter establishments, NSIS, informed by [its] experiences under [the HIMP pilot].” 84 Fed. Reg. at 52300. USDA also stated its reasons, *i.e.*, “to improve the effectiveness of market hog slaughter inspection; make better use of [FSIS’s] resources; and remove unnecessary regulatory obstacles to industry innovation.” *Id.*; *see also id.* at 52303-04 (elaborating on these points); AR102023-24. USDA further explained that NSIS had potential to “facilitate pathogen reduction in pork products and improve compliance with the Humane Methods of Slaughter Act,” 84 Fed. Reg. at 52300, and predicted that the Final Rule would result in a net benefit of approximately \$62 million over 10 years, *see id.* at 52338-41. In the face of these express acknowledgments by USDA that it was offering a new slaughter inspection system to all interested market hog slaughter establishments and USDA’s explanation of its reasoning for doing so, any argument that Defendants arbitrarily and unlawfully “reversed” position is meritless.

### CONCLUSION

For the foregoing reasons, Defendants’ Cross-Motion for Summary Judgment should be granted, Plaintiffs’ Motion for Summary Judgment should be denied, and summary judgment should be entered for Defendants on the remaining claim asserted by Plaintiffs in this action.

Dated: November 18, 2022

Respectfully submitted,

BRIAN M. BOYNTON

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<sup>13</sup> Such a response would, of course, entail a claim significantly broader than the one remaining in this case, which targets only the ante-mortem inspection provisions of the Final Rule. *See* FAC ¶¶ 174-81; *see also* Stipulated Dismissal, ECF No. 79; Order, ECF No. 80.

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